

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
7 June 2001 (07.06.2001)

PCT

(10) International Publication Number  
**WO 01/39831 A1**

(51) International Patent Classification<sup>7</sup>: A61N 1/372, 1/34

(72) Inventors: MANN, Carla, M.; 339 N. Sycamore, #6, Los Angeles, CA 90036 (US). MEADOWS, Paul, M.; 5030 N. Hill Street, La Canada, CA 91011-2335 (US).

(21) International Application Number: PCT/US00/31612

(22) International Filing Date:  
16 November 2000 (16.11.2000)

(74) Agent: GOLD, Bryant, R.; Advanced Bionics Corporation, 12740 San Fernando Road, Sylmar, CA 91342 (US).

(25) Filing Language: English

(81) Designated States (national): AU, CA, JP.

(26) Publication Language: English

(84) Designated States (regional): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

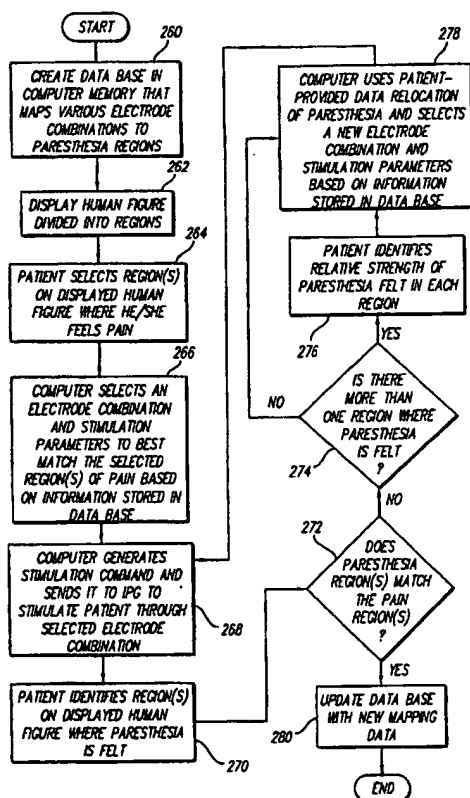
(30) Priority Data:  
60/169,129 6 December 1999 (06.12.1999) US

Published:  
— With international search report.

(71) Applicant: ADVANCED BIONICS CORPORATION  
[US/US]; 12740 San Fernando Road, Sylmar, CA 91342 (US).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPLANTABLE DEVICE PROGRAMMER



(57) Abstract: A patient and/or a clinician may program an implant device, e.g., an implanted spinal cord stimulator (SCS), through the use of a programming computer, or clinician programmer, linked with the implant device. Data is initially stored in the computer that relates to known information regarding the anatomical relationships between the spine and the body. The body is divided into dermatomes and/or subdivisions of dermatomes, and a representation of the body, including its dermatomes and/or subdivisions of dermatomes are displayed on the screen (or other display device) associated with the computer. The patient moves a cursor over the regions of the body displayed on the computer screen to select the region of pain, or a region of paresthesia, by a click of a mouse or the press of a button. The patient may select as many dermatomes or body segments/regions/subdivisions as necessary to communicate the area of pain or paresthesia to the computer. The computer uses the patient-provided information, as well as the pre-programmed data therein, to quickly zero in on an electrode combination and appropriate stimulus parameters that create a match (or as close of a match as is possible) between the pain region and the paresthesia region.

WO 01/39831 A1

## IMPLANTABLE DEVICE PROGRAMMER

### BACKGROUND OF THE INVENTION

5           The present invention relates to implantable medical devices, and more particularly to a programmer used to program such medical devices. In a preferred application, the invention relates to a programmer adapted for use with an implantable spinal cord stimulator (SCS), or similar implantable stimulator.

10           Many types of implantable nerve stimulators exist which perform the function of providing selected electrical stimulation through selected groupings of implanted electrodes. An example of such a nerve stimulator is a spinal cord stimulator.

15           Spinal cord stimulation systems offer a large number of variables to be programmed. For example, in addition to the variables of stimulation frequency and stimulation current amplitude, the number of electrode contacts that provide the stimulation must be programmed. Moreover, because such selected electrode contacts are typically selected from a relatively large number of contacts, with the number of possible electrode combinations being a large number, there is a need to determine which electrode combination from such large number of possible combinations, provides the optimum stimulation performance for the patient. That is, after initial implantation, 20 it is typically necessary to program many electrode combinations and to test the patient response to each combination. This can be a very time consuming task, both to perform the selected programming of all the electrode combinations, and then to conduct the testing for each selected combination. Optimal device settings, i.e., an optimal electrode combination, is highly dependent upon the location and distribution of stimulating current provided through the selected electrode combination relative to various nerve paths of the body, which in turn varies significantly from patient to patient. Thus, one selected electrode combination that proves effective for one patient, may not prove effective for another patient. Hence, many different electrode combinations must be programmed and tested in a relatively short period of time in order to discover which 25 electrode combination is most effective for a given patient.

30           Heretofore, the process of optimizing the stimulator device settings has typically involved having the programming clinician simply select an electrode combination and stimulation settings, wait for a patient response, and then intuitively or arbitrarily make changes to the programming in response to patient feedback, wherein the goal is to affect the pain site by paresthesia. (Herein, "paresthesia" is a term used to describe the tingling sensation felt by a patient as a result of application of an electrical stimulus.) Much research has been published showing spinal cord mapping in relation to anatomical areas and neurophysiologic responses to help understand how

- 2 -

best electrode arrays should be set up, or programmed, for effective stimulation. Spinal cord mapping has also been associated to dermatome segments of the body.

In U.S. Patent Number 5,370,672, one way is taught by which an implanted device may be programmed. In accordance with the teachings of the '672  
5 patent, a patient is provided with a touch sensitive screen on which a representation of the human body is presented. The touch sensitive screen is connected to a suitable computer, and the computer is linked with the implanted device, i.e., stimulus commands may be sent from the computer to the implanted device. The patient then  
10 draws a circle around the area of pain he or she is experiencing on the touch sensitive screen using a stylus or other suitable tool. Acting on that information, the computer sends commands to the stimulator to activate an electrode combination in the vicinity of the identified pain area. The patient then draws another circle on the touch sensitive  
15 screen indicating where he or she feels the paresthesia resulting from the applied stimulus. The computer then calculates, using predetermined rules, a new electrode combination in an attempt to bring the paresthesia drawing closer to the pain drawing, and then sends a new command to the stimulator to cause it to apply an electrical  
20 stimulus to the new electrode combination. The patient responds by drawing another circle on the touch sensitive screen indicating where he or she feels the paresthesia resulting from the stimulus applied to the newly selected electrode combination. This process continues, using the paresthesia location information provided by the patient after stimulating each new electrode combination, in an attempt to bring or move the paresthesia-patient-identified area on the touch sensitive screen over the pain area, initially identified on the touch sensitive screen by the patient. Disadvantageously, this approach requires additional hardware in addition to the programming computer,  
25 including a touch sensitive screen and a stylus.

What is needed is a more streamlined approach for programming an implanted device that does not require the use of additional hardware other than the programming computer.

#### BRIEF SUMMARY OF THE INVENTION

30 The present invention addresses the above and other needs by allowing a patient to program an implant device, e.g., an implanted spinal cord stimulator (SCS), through the use of a programming computer, e.g., a laptop or personal handheld computer, linked with the implant device. The computer is programmed to utilize information known in the art regarding anatomical relationships between the spine and  
35 the body. The body is divided into dermatomes and/or subdivisions of dermatomes, and a representation of the body, including its dermatomes and/or subdivisions of dermatomes are displayed on the screen (or other display device) associated with the

computer. The patient then moves a cursor over the regions of the body displayed on the computer screen. As the patient thus moves the cursor over regions of the body, dermatomes or body subdivisions are exposed, allowing the patient to select the region of pain or paresthesia by a click of a mouse or the press of a button. For example, in  
5 one implementation, the patient may select a region of pain by a right mouse click, and a region of paresthesia by a left mouse click. Advantageously, the patient may select as many dermatomes or body segments/regions/subdivisions as necessary to communicate the area of pain or paresthesia to the computer. The computer then uses this information to quickly zero in on an electrode combination and appropriate stimulus  
10 parameters so as to create a match (or as close of a match as is possible) between the pain region and the paresthesia region.

In accordance with one aspect of the invention, the invention is directed to a method of programming an implant device. The implant device typically comprises an implantable pulse generator having an implantable electrode array connected  
15 thereto. The implantable pulse generator has electrical circuitry therein that generates electrical stimulation pulses in accordance with programming data. The electrical stimulation pulses are delivered to body tissue of a patient through a selected combination of a multiplicity of electrodes on the electrode array. The programming method generally includes the following steps:

- 20 (a) creating a data base that maps various electrode combinations to paresthesia regions of the body based on known and collected data;
- (b) storing the data base in a programming computer;
- (c) displaying a human figure on a display screen of the programming computer, and dividing the human figure into a multiplicity of  
25 regions;
- (d) selecting one region on the displayed human figure where the patient feels pain;
- (e) selecting a combination of electrodes and stimulation parameters adapted to produce paresthesia in region of pain;
- 30 (f) generating stimulation pulses and delivering the stimulation pulses to the selected combination of electrodes through the implantable pulse generator;
- (g) identifying a region of paresthesia on the displayed human figure where the stimulation pulses generated in step (f) produce paresthesia;
- 35 (h) determining the degree of mismatch between the region of paresthesia identified in step (f) and the region of pain selected in step (d);
- (i) if the degree of mismatch exceeds a prescribed level, selecting a new combination of electrodes and stimulation parameters based on the

- 4 -

identified region of paresthesia and the degree of mismatch, and repeating steps (f), (g) and (h); and

(i) if the degree of mismatch is less than the prescribed level, programming the implantable pulse generator with the programming data that produces the least mismatch.

In accordance with another aspect of the invention, the invention is directed to a system for programming an implantable pulse generator. The implantable pulse generator has an implantable electrode array connected thereto. Further, the implantable pulse generator has electrical circuitry therein that generates electrical stimulation pulses in accordance with programming data. These electrical stimulation pulses may be delivered to body tissue of a patient through a selected combination of a multiplicity of electrodes on the electrode array. The system for programming comprises:

(a) a programming computer linked to the implantable pulse generator. The programming computer has a display screen, and includes means for generating and displaying a cursor on the screen that may be manually moved around on the screen by a user.

(b) means in the computer for displaying a human figure on the display screen, where the human figure is divided into a multiplicity of regions.

(c) means coupled to the computer for selecting a region on the displayed human figure where the patient feels pain. If necessary, more than one region may be selected (e.g., if the patient feels pain in more than one region).

(d) means in the computer for automatically selecting a combination of electrodes and stimulation parameters adapted to produce paresthesia in the selected region(s) of pain. This selection will initially be made based on information previously programmed into the computer, e.g., a data base, that defines known anatomical relationships between the spine and the body.

(e) means for generating stimulation pulses and delivering the stimulation pulses to the selected combination of electrodes through the implantable pulse generator.

(f) means in the computer for identifying a region(s) of paresthesia on the displayed human figure where the stimulation pulses generated in step (e) produce paresthesia.

(g) means in the computer for determining the degree of mismatch between the identified region(s) of paresthesia and the selected region(s) of pain.

- 5 -

(h) means in the computer for selecting a new combination of electrodes and stimulation parameters based on the identified region(s) of paresthesia and the degree of mismatch if the degree of mismatch exceeds a prescribed level. Then, generating stimulation pulses using the new combination of electrodes and stimulation parameters and determining a new degree of mismatch between the pain and paresthesia regions. This process is then repeated as necessary, thereby minimizing in an iterative fashion the degree of mismatch.

(i) means for programming the implantable pulse generator with the programming data that produces the least mismatch.

In accordance with yet another aspect of the invention, the invention is directed to a system for programming an implantable pulse generator. The implantable pulse generator comprises electrical circuitry that generates electrical stimulation pulses in controlled by programming data stored in the computer. An electrode array having a multiplicity of electrodes is coupled to the electrical circuitry. The programming system in accordance with this aspect of the invention includes the following elements:

(1) a programming computer linked to the implantable pulse generator, where the programming computer has a display screen, and means for generating and displaying a cursor on the display screen that may be manually moved around on the display screen by a user;

(2) first program data stored in the programming computer that causes a human figure to be displayed on the display screen, where the human figure is divided into a multiplicity of regions;

(3) means coupled to the cursor for selecting at least one region on the displayed human figure as a location where the patient feels pain;

(4) second program data stored in the programming computer that causes a combination of electrodes and stimulation parameters to be selected that are adapted to produce paresthesia in the same general location where the patient feels pain;

(5) third program data stored in the programming computer that determines the degree of mismatch between the location where the patient feels pain and the location where the patient feels paresthesia as a result of stimulation pulses produced by the second program data;

(6) fourth program data stored in the programming computer that causes a new combination of electrodes and stimulating parameters to be selected that are adapted to minimize the degree of mismatch between the location where the patient feels pain and the location where the patient feels paresthesia as a result of recently applied stimulation pulses; and

- 6 -

(7) fifth program data stored in the programming computer that causes the combination of electrodes and stimulation parameters that minimize the degree of mismatch to be included in the programming data that thereafter controls the operation of the implantable pulse generator.

5 It is thus a feature of the present invention to provide a programming device for use with an implantable stimulator, such as an implantable spinal cord stimulator, that allows the patient to easily identify a region of pain and then a region of paresthesia, so that the programming device may then automatically change the selected stimulation parameters, including the selected combinations of electrodes, to  
10 cause the region of paresthesia to overlap or merge with the region of pain, thereby alleviating the pain.

### BRIEF DESCRIPTION OF THE DRAWINGS

The above and other aspects, features and advantages of the present invention will be more apparent from the following more particular description thereof,  
15 presented in conjunction with the following drawings wherein:

FIG. 1 is a block diagram that illustrates the various implantable, external, and surgical components of a representative implantable stimulation system;

FIG. 2 illustrates examples of various types of electrode arrays that may be used with the system of FIG. 1;

20 FIG. 3 is a timing waveform diagram that depicts representative current waveforms that may be applied to various ones of the electrode contacts of the electrode arrays through one or more stimulus channels;

FIG. 4 is a block diagram that illustrates the main components of a representative implantable pulse generator (IPG) that may be used with the invention;

25 FIG. 5 illustrates a type of hand-held programmer that may be used to program the implantable pulse generator;

FIG. 6 depicts a representative programming screen that may be used as part of the programming system features of the invention;

30 FIGS. 7A, 7B, 7C and 7D show the display of a human body, divided into regions, dermatomes, or other subdivisions of the body, which display is presented on the programming screen, and further illustrate an exemplary sequence of selections made by a patient as the invention is used to match a region of pain with a region of paresthesia; and

35 FIG. 8 is a flow chart that depicts the main steps associated with programming an implant device in accordance with the present invention.

Corresponding reference characters indicate corresponding components throughout the several views of the drawings.

### DETAILED DESCRIPTION OF THE INVENTION

The following description is of the best mode presently contemplated for carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention.

5           At the outset, it is emphasized that the present invention relates to an implantable device programmer, i.e., a method or system for programming an implant device so that it carries out a desired function. The invention will be described with reference to the implanted pulse generator (IPG) used as part of a spinal cord stimulation (SCS) system. It is to be understood, however, that the present invention  
10 is not limited for use just within an SCS system. Rather, the invention has broad applicability, and may be used with numerous different types of implant devices and systems used to alleviate pain or produce other desired results, and wherein feedback from the patient regarding areas or regions where paresthesia or other sensations are felt as a result of an applied stimulus may be obtained. Such systems may include all  
15 types of neural stimulators and sensors, deep brain stimulators, cochlear stimulators, drug delivery systems, muscle tissue stimulators, and the like.

Turning first to FIG. 1, there is shown a block diagram that illustrates the various components of an exemplary SCS system. These components may be subdivided into three broad categories: (1) implantable components 10, (2) external  
20 components 20, and (3) surgical components 30. As seen in FIG. 1, the implantable components 10 include an implantable pulse generator (IPG) 100, an electrode array 110, and (as needed) an extension 120. The extension 120 is used to electrically connect the electrode array 110 to the IPG 100. The IPG 100, described more fully below in connection with FIG. 4, comprises a rechargeable, multichannel, telemetry-  
25 controlled, pulse generator housed in a rounded titanium case. A suitable connector allows the electrode array 110 or extension 120 to be detachably secured, i.e., electrically connected, to the IPG 100.

The IPG 100 contains stimulating electrical circuitry ("stimulating electronics"), a power source, e.g., a rechargeable battery, and a telemetry system.  
30 Typically, the IPG 100 is placed in a surgically-made pocket either in the abdomen, or just at the top of the buttocks. It may, of course, also be implanted in other locations of the patient's body. Once implanted, the IPG 100 is connected to the lead system, comprising the lead extension 120, if needed, and the electrode array 110. The lead extension 120, for example, may be tunneled up to the spinal column. Once implanted,  
35 the lead system 110 and lead extension 120 are intended to be permanent. In contrast, the IPG 100 may be replaced when its power source fails or is no longer rechargeable.

Advantageously, the IPG 100 can provide electrical stimulation through a multiplicity of electrodes, e.g., sixteen electrodes, included within the electrode array

- 8 -

110. Different types of electrode arrays 110 that may be used with the invention are depicted in FIG. 2. A common type of electrode array 110, for example, is the "in-line" lead, as shown at (A), (B), and (C) in FIG. 2. An in-line lead includes individual electrode contacts 114 spread longitudinally along a small diameter flexible cable or carrier 116. The flexible cable or carrier 116 has respective small wires embedded (or otherwise carried) therein for electrically contacting each of the individual electrode contacts. The advantage of an in-line lead relates to its ease of implantation, i.e., it can be inserted into the spinal canal through a small locally-anesthetized incision while the patient is kept awake. When the patient is awake, he or she can provide valuable feedback as to the effectiveness of stimulation applied to a given electrode contact or contacts 114 for a given positioning of the array 110. One of the disadvantages of the in-line lead is that it is prone to migrating in the epidural space, either over time or as a result of a sudden flexion movement. Such migration can disadvantageously change the location and nature of the paresthesia and the required stimulation level. Either both of the these conditions may require reprogramming of the IPG 100 and/or surgical correction (repositioning) of the electrode array 110. Note, as used herein, the term "paresthesia" refers to that area or volume of the patient's tissue that is affected by the electrical stimuli applied through the electrode array. The patient may typically describe or characterize the paresthesia as an area where a tingling sensation is felt.

To overcome the migration problems associated with an in-line electrode, a different type of electrode array 110 may be used, known as a paddle lead. Various types of paddle leads are illustrated at (D), (E), (F) and (G) of FIG. 2. In general, each type of paddle lead is shaped with a wide platform 119 on which a variety of electrode contact configurations or arrays are situated. For example, the paddle lead shown at (D) in FIG. 2 has two columns of four rectangular-shaped electrode contacts 115 carried on a wide platform 119, with the electrode contacts in one column being offset from the electrode contacts in the other column. (Here, the term "offset" refers to the vertical position of the electrode contacts, as the leads are oriented in FIG. 2.) The flexible cable or carrier 116 carries wires from each electrode contact to a proximal end of the paddle lead (not shown), where such wires may be connected to the IPG 100 (or to a lead extension 119, which in turn connects to the IPG 100). The paddle lead shown at (E) in FIG. 2 similarly has two columns of eight electrode contacts 115 in each row, with the electrode contacts in one column being offset from the electrode contacts in the other column, and with each electrode contact being connected to one or more wires carried in the flexible cable or carrier 116.

Still referring to FIG. 2, other types of paddle leads are illustrated. As seen at (F) in FIG. 2, one type of paddle lead has its carrier or cable 116 branch into two separate branches 117a and 117b, with a wide platform 119a and 119b being located

- 9 -

at a distal end of each branch. Within each wide platform 119a and 119b an array of at least two circular-shaped electrode contacts 115' is situated. As seen in (G) in FIG. 2, another type of paddle lead has a wide platform 119 at its distal end on which a single column of circular-shaped electrode contacts 115' is situated.

5                    Whichever type of lead and electrode array is used, an important feature of the SCS system shown in FIG. 1 is the ability to support more than one lead with two or more channels. Here, a "channel" is defined as a specified electrode, or group of electrodes, that receive a specified pattern or sequence of stimulus pulses. Thus, where more than one "channel" is available, each channel may be programmed to  
10                   provide its own specified pattern or sequence of stimulus pulses to its defined electrode or group of electrodes. In operation, all of the stimulus patterns applied through all of the channels of such multi-channel system thus combine to provide an overall stimulation pattern that is applied to the tissue exposed to the individual electrodes of the electrode array(s).

15                   There are many instances when it is advantageous to have multiple channels. For example, left and right sides, or upper and lower extremities, may require different stimulus parameter settings. Low back pain typically requires a different stimulation site and stimulation parameters than any of the extremities. Moreover, many patients exhibit conditions better suited to horizontal stimulation paths,  
20                   while other patients may have conditions better suited to vertical stimulation paths. Therefore, having multiple channels that may be connected to multiple electrodes, positioned within one or more electrode arrays, so as to cover more tissue/nerve area, greatly facilitates providing the type of stimulation pattern and stimulation parameters needed to treat a particular patient.

25                   One type of preferred electrode configuration uses a multiple lead system, e.g., two or four leads, with the leads placed side by side, or at different vertical locations. The individual electrodes on each vertical lead of such multiple lead system effectively create a desired electrode array that covers a large, or relatively large, tissue area. The respective electrodes of each vertical lead may be aligned horizontally, offset  
30                   horizontally, or randomly or systematically arranged in some other pattern.

                    The electrode array 110 and its associated lead system typically interface with the implantable pulse generator (IPG) 100 via a lead extension system 120. As needed, e.g., for testing and/or fitting purposes, the electrode array 110 may also interface with an external trial stimulator 140 through one or more percutaneous lead  
35                   extensions 132, connected to the trial stimulator 140 through an external cable 134. In this manner, the individual electrodes included within the electrode array 110 may receive an electrical stimulus from either the trial stimulator 140 or the IPG 100.

- 10 -

As suggested in the block diagram of FIG. 1, the lead extension(s) 120, as well as the percutaneous extension(s) 132 are inserted through the patient's tissue through the use of appropriate surgical components 30, and in particular through the use of tunneling tools 152, as are known in the art, or as are especially developed for purposes of spinal cord stimulation systems. In a similar manner, the electrode array 110 is implanted in its desired position, e.g., adjacent the spinal column of the patient, through the use of an insertion needle 154 and a guide wire 156.

The operation of multiple channels used to provide a stimulus pattern through multiple electrodes is illustrated in FIG. 3. FIG. 3 assumes the use of an electrode array 110 having sixteen electrodes connected to the implantable pulse generator (IPG) 100. In addition to these sixteen electrodes, which are numbered E1 through E16, a case electrode (or return electrode) is also available. In FIG. 3, the horizontal axis is time, divided into increments of 1 millisecond (ms), while the vertical axis represents the amplitude of a current pulse, if any, applied to one of the sixteen electrodes. Thus, for example, at time  $t=0$  ms, FIG. 3 illustrates that a current pulse of 4 milliamps (mA) appears on channel 1 at electrode E1 and E3. FIG. 3 further shows that this current pulse is negative (-4mA) on electrode E1 and positive (+4mA) on electrode E3. Additionally, FIG. 3 shows that the stimulation parameters associated with this current pulse are set at a rate of 60 pulses per second (pps), and that the width of the pulse is about 300 microseconds ( $\mu$ s).

Still with reference to FIG. 3, it is seen that at time  $t=2$  ms, channel 2 of the IPG 100 is set to generate and apply a 6 mA pulse, having a repetition rate of 50 pps and a width of 300  $\mu$ s, between electrode E8 (+6 mA) and electrodes E6 and E7 (-4 mA and -2 mA, respectively). That is, channel 2 of the IPG supplies a current pulse through electrode E8 (+6 mA) that is shared on its return path through electrode E6 (-4 mA) and electrode E7 (-2 mA).

As further seen in FIG. 3, at time  $t=4$  ms, channel 3 of the IPG 100 is set to generate and supply a 5 mA pulse to electrode E10 (+5 mA) which is returned through electrode E8 (-5 mA). This pulse has a rate of 60 pps, and a width of 400  $\mu$ s. Similarly, it is seen that at time  $t=6$  ms, channel 4 of the IPG is set to generate and supply a 4 mA pulse to electrode E14 (+4 mA) which is returned through electrode E13 (-4 mA). This channel 4 pulse has a rate of 60 pps and a width of 300  $\mu$ s.

The particular electrodes that are used with each of the four channels of the IPG 100 illustrated in FIG. 3 are only exemplary of many different combinations of electrode pairing and electrode sharing that could be used. That is, any channel of the IPG may be programmably connected to any grouping of the electrodes, including the reference (or case) electrode. While it is typical that only two electrodes be paired together for use by a given channel of the IPG, as is the case with channels 1, 3 and

4 in the example of FIG. 3, it is to be noted that any number of electrodes may be grouped and used by a given channel. When more than two electrodes are used with a given channel, the sum of the current sourced from the positive electrodes should be equal to the sum of the current sunk (returned) through the negative electrodes, as is the case with channel 2 in the example of FIG. 3 (+6 mA sourced from electrode E8, and a total of -6 mA sunk to electrodes E6 [-4 mA] and E7 [-2 mA]).

Turning next to FIG. 4, a block diagram is shown that illustrates the main components of an implantable pulse generator, or IPG, 100 used with a representative SCS system. As seen in FIG. 4, the IPG includes a microcontroller ( $\mu$ C) 160 connected to memory circuitry 162. The  $\mu$ C 160 typically comprises a microprocessor and associated logic circuitry, which in combination with control logic circuits 166, timer logic 168, and an oscillator and clock circuit 164, generate the necessary control and status signals which allow the  $\mu$ C to control the operation of the IPG in accordance with a selected operating program and operational parameter set (OPS). The operational parameter set for an IPG 100 of the type shown in FIG. 4 includes parameter values that define, e.g., pulse amplitude, pulse width (duration), channel frequency, electrode configuration, ramp rate, treatment (stimulation) time, and the like. The operating program and OPS are programmably stored within different locations of the memory 162 by transmitting an appropriate modulated carrier signal through a receiving coil 170 and charging and forward telemetry circuitry 172 from an external programming unit, e.g., a handheld programmer 202 and/or a clinician programmer 204, assisted as required through the use of a directional device 206 (see FIG. 1). (The handheld programmer is thus considered to be in "telecommunicative" contact with the IPG; and the clinician programmer is likewise considered to be in telecommunicative contact with the handheld programmer, and through the handheld programmer, with the IPG.) The charging and forward telemetry circuitry 172 demodulates the carrier signal it receives through the coil 170 to recover the programming data, e.g., the operating program and/or the OPS, which are then stored within known addresses of the memory 162, or within other memory elements (not shown) distributed throughout the IPG 100.

The microcontroller 160 is further coupled to monitoring circuits 174 via bus 173. The monitoring circuits 174 monitor the status of various nodes or other points 175 throughout the IPG 100, e.g., power supply voltages, current values, temperature, the impedance of electrodes attached to the various electrodes E1...En, and the like. Informational data sensed through the monitoring circuit 174 may be sent to a remote location external the IPG (e.g., a non-implanted location) through back telemetry circuitry 176, including a transmission coil 177.

The operating power for the IPG 100 is derived from a replenishable power source 180, e.g., a rechargeable battery and/or a supercapacitor. Such power

source 180 provides an unregulated voltage to power circuits 182. The power circuits 182, in turn, generate the various voltages 184, some of which are regulated and some of which are not, as needed by the various circuits located within the IPG. The power circuits 182 further selectively direct energy contained within the carrier signal, obtained  
5 through the charging and forward telemetry circuit 172, to the replenishable power source 180 during a charging mode of operation. In this way, the power source 180 may be recharged when needed.

In one embodiment, the power source 180 of the IPG 100 comprises a rechargeable battery. Recharging occurs inductively from an external charger to an  
10 implant depth of approximately 2-3 cm.

Additionally, the IPG 100 is able to monitor and telemeter the status of its replenishable power source 180 (e.g., rechargeable battery) each time a communication link is established with the external patient programmer 202. Such monitoring not only identifies how much charge is left, but also charge capacity.  
15 Typically, a telecommunicative link is established, and hence battery monitoring may occur, each time a programming event occurs, i.e., each time the patient or medical personnel change a stimulus parameter.

The power circuits 182 advantageously include protection circuitry that protects the replenishable power source 180 from overcharging. Also, safeguarding  
20 features are incorporated that assure that the power source is always operated in a safe mode upon approaching a charge depletion. Potentially endangering failure modes are avoided and prevented through appropriate logic control that is hard-wired into the device, or otherwise set in the device in such a way that the patient cannot override them.

Variations of the charging scheme shown in FIG. 4 may also be used. For example, instead of charging through the coil 170 and the Charging and Forward Telemetry circuit 172, charging may occur through a separate charging coil and circuit (not shown), or through the back-telemetry coil 177 (connected to appropriate circuitry for rectifying the received power and passing it on to the power circuits 182).  
25

Still with reference to FIG. 4, it is seen that a plurality  $m$  of independent current source pairs,  $186+I1$ ,  $186-I1$ ,  $186+I2$ ,  $186-I2$ ,  $186+I3$ ,  $186-I3$ , ...  $186+Im$ ,  $186-Im$  are coupled to the control logic 166 via control bus 167. One current source of each pair of current sources functions as a positive (+) current source, while the other current source of each pair functions as a negative (-) current source. The output of the  
35 positive current source and the negative current source of each pair of current sources 186 is connected to a common node 187. This common node 187, in turn, is connected through a low impedance switching matrix 188 to any of  $n$  electrode nodes  $E1$ ,  $E2$ ,  $E3$ , ...  $En$ , through respective coupling capacitors  $C1$ ,  $C2$ ,  $C3$ , ...  $Cn$ . Through appropriate

control of the switching matrix 188, any of the  $m$  current source nodes 187 may be connected to any of the electrode nodes  $E_1, E_2, E_3, \dots E_n$ . Thus, for example, it is possible to program the current source 186+I1 to produce a pulse of +4 mA (at a specified rate and for a specified duration), and to synchronously program the current  
5 source 186-I2 to similarly produce a pulse of -4 mA (at the same rate and pulse width), and then (through the switching matrix 188) connect the 186+I1 node to electrode node  $E_3$  and the 186-I2 node to electrode node  $E_1$  at relative time  $t=0$  ms (and at a recurring rate thereafter) in order to realize the operation of channel 1 depicted in the timing diagram of FIG. 3. In a similar manner, the operation of channels 2, 3 and 4 shown in  
10 FIG. 3 may likewise be realized.

As described, it is thus seen that any of the  $n$  electrodes may be assigned to up to  $k$  possible groups (where  $k$  is an integer corresponding to the number of channels, and in a preferred embodiment is equal to 4). Moreover, any of the  $n$  electrodes can operate, or be included in, any of the  $k$  channels. The channel identifies  
15 which electrodes are selected to synchronously source or sink current in order to create an electric field. Amplitudes and polarities of electrodes on a channel may be adjusted, e.g., as controlled by the current operational parameter set (OPS) used by the IPG. The OPS also typically assigns a pulse rate and pulse width for the electrodes of a given channel.

20 Hence, it is seen that each of the  $n$  programmable electrode contacts can be programmed, through a selected OPS, to have a positive (sourcing current), negative (sinking current), or off (no current) polarity in any of the  $k$  channels.

Moreover, it is seen that each of the  $n$  electrode contacts can operate in a bipolar mode or multipolar mode, e.g., where two or more electrode contacts are  
25 grouped to source/sink current at the same time. Alternatively, each of the  $n$  electrode contacts can operate in a monopolar mode where, e.g., the electrode contacts associated with a channel are configured as cathodes (negative), and the case electrode, on the IPG case, is configured as an anode (positive). The mode of the electrode contacts that is to be used, e.g., bipolar, multipolar or monopolar, may also  
30 be defined by a specific parameter included within the current OPS.

Further, the amplitude of the current pulse being sourced or sunk from a given electrode contact may be programmed to one of several discrete levels. These discrete levels may be similarly defined by a specific parameter, or a specific group of parameters, included within the current OPS. In one embodiment, the currents can be  
35 individually set from  $\pm 0$  to  $\pm 10$  mA, in steps of 0.1 mA. The current output capacity of individual electrodes are limited when operating with more than one other electrode of the same polarity in a given channel in order to assure that the maximum current values are maintained. Additionally, in order to prevent "jolts", amplitude changes are always

gradually changed, e.g., in a ramping fashion, at a specified "ramp rate", between the value range between the settings. The ramp rate may also be defined by a specific parameter included within the current OPS. Such ramping feature may also be used when initially powering on the IPG, thereby preventing full magnitude stimulus pulses  
5 from being delivered to the patient during a ramping-up time period. The ramp rate may be different, as defined by the current OPS, depending upon the channel and programmed amplitude, between about 1 and 10 seconds.

Also, the pulse width of the current pulses is typically adjustable in convenient increments. As with the other operational parameters associated with the  
10 IPG, the pulse width may be defined by a specific parameter included within the current OPS. The pulse width range is preferably at least 0 to 1 ms in increments of 10  $\mu$ s. Generally, it is preferred that the pulse width be equal for all electrodes in the same channel.

Similarly, the pulse rate is adjustable within acceptable limits. The pulse  
15 rate may likewise be defined by an appropriate parameter included within the current OPS. The pulse rate preferably spans at least two ranges: (1) a normal rate; and (2) a high rate. The normal rate range covers 0-150 pps per channel in approximately 1 pps increments. The high rate range covers 100-500 pps in increments of approximately 10 pps, and need only be available on one or two channels. When used, the high rate  
20 range limits operation of the additional channels at the normal rates when stimulation and/or power conflicts are determined to be present.

Because the IPG 100 may have a limit as to how much current it can source or sink at any given time, e.g., a representative IPG may only be capable of delivering current pulses up to  $\pm 20$  mA in amplitude at any instant in time, the SCS  
25 system also regulates the channel rates to prevent overlap (i.e., to prevent two or more pulses from different channels from occurring at the same time). Such channel rate regulation is transparent to the patient.

The stimulation pulses generated by the IPG 100 must also be charged balanced. This means that the amount of positive charge associated with a given  
30 stimulus pulse must be offset with an equal and opposite negative charge. Charge balance may be achieved through a coupling capacitor, which provides a passive capacitor discharge that achieves the desired charge balanced condition. Such passive capacitor discharge is evident in the waveforms depicted in FIG. 3 as the slowly decaying waveform following the short trailing edge of each pulse. Alternatively, active  
35 biphasic or multiphasic pulses with positive and negative phases that are balanced may be used to achieve the needed charge balanced condition.

In some embodiments of the invention, a real-time clock is also incorporated within the timing circuits of the IPG 100. Such real-time clock

advantageously allows a run schedule to be included within the current OPS. That is, the patient can schedule auto-run times for IPG operation at certain times of the day. When an auto-run time begins, all channels are enabled and provide a previously-programmed pattern of stimulus currents, i.e., current pulses having a programmed  
5 width, rate, and amplitude are generated and delivered through each channel. The auto-run time continues for a set time period, e.g., several hours, or for only a few minutes. Advantageously, the auto-run time is defined by the current OPS. Thus, when a new OPS is selected to replace an existing OPS, the new OPS controls operation of the IPG thereafter, including any auto-run time that may be defined in the  
10 new OPS.

An important feature included within the IPG 100 is its ability to measure electrode impedance, and to transfer the impedance thus measured back to a remote programmer, or other processor, through the back telemetry circuits 176. Also, the microcontroller 160, in combination with the other logic circuits, may also be  
15 programmed to use the electrode impedance measurements to adjust compliance voltages and to thereby better maintain low battery consumption. In one preferred embodiment of the IPG 100, electrode impedance is measured for each electrode contact by sourcing or sinking a 4 mA current pulse from the electrode contact to the case electrode, measuring the voltage at the electrode contact, and computing the  
20 resulting impedance. (Impedance is equal to voltage/current.) For a spinal cord implantation, the electrode impedance will typically range between about 400 ohms and 600 ohms.

Advantageously, as configured in FIG. 4, the IPG 100 is able to individually control the  $n$  electrode contacts associated with the  $n$  electrode nodes E1, E2, E3, ... E $n$ . Controlling the current sources and switching matrix 188 using the  
25 microcontroller 160, as defined by individual operational parameters included within the current OPS, in combination with the control logic 166 and timer logic 168, thereby allows each electrode contact to be paired or grouped with other electrode contacts, including the monopolar case electrode, in order to control the polarity, amplitude, rate,  
30 pulse width and channel through which the current stimulus pulses are provided.

As shown in FIG. 4, much of circuitry included within the IPG 100 may be realized on a single application specific integrated circuit (ASIC) 190. This allows the overall size of the IPG 100 to be quite small, and readily housed within a suitable hermetically-sealed case. The IPG 100 includes  $n$  feedthroughs to allow electrical  
35 contact to be individually made from inside of the hermetically-sealed case with the  $n$  electrodes that form part of the lead system outside of the case. The IPG case is preferably made from titanium and is shaped in a rounded case. A exemplary rounded IPG case has a maximum circular diameter of about 50 mm, and preferably only about

45 mm (or equivalent area). Thus, the implant case has smooth curved transitions that minimize or eliminate edges or sharp corners. The maximum thickness of the case is about 10 mm, and is preferably only about 8 mm.

It is thus seen that the implant portion 10 of the SCS system (see FIG. 1) includes an implantable pulse generator (IPG) 100 as described in FIG. 4. Such IPG further includes stimulating electronics (comprising programmable current sources and a switching matrix and associated control logic), a power source, and a telemetry system. Advantageously, the power source may be recharged over and over again, as needed, and may thus provide a long life, as well as a high current output capacity.

It is thus seen that an important feature of the present invention is its ability to map current fields through selective control of the current sources which are attached to each electrode node. In one preferred embodiment, the invention achieves its desired function of being able to independently map a desired current to each electrode node through the use of a microcontroller 160, one or more ASIC's, at least eight constant current generators, a low impedance switching matrix, timers and control registers, and a state machine architecture. The ASIC has a standard bus interface to the microcontroller allowing simple, direct and efficient access to all of its control and stimulation parameter registers. Each current generator is independent of the other generators, but any of the generators may be linked in the triggering (control) circuitry and/or their outputs may be linked in the switching matrix. Triggering and timing control circuitry allow the simultaneous activation of any of the channels. A low impedance switching matrix advantageously allows the mapping of each current generator's two outputs to be assigned to any of the pulse generator electrode nodes (or leadwires, which are attached to the electrode nodes) or to the case. In this manner, one or more current generators may be attached to any one or more electrode nodes (leadwires) and thus electrodes, and conversely, any electrode node (leadwire) may be attached to one or more current generator outputs; grounded, or left open. The significance of the biphasic, or (in some instances) multiphasic, nature of the stimulation pulses is that currents may be actively driven in either the anodic or cathodic direction to the output electrode nodes of the current generators. This feature along with the matrix switching of output leads allows the creation of "virtual" electrodes and stimulation current field control, not possible with other known designs. This feature thus provides an important advance in the ability to direct the stimulation pulses to pools of target neurons in the spinal cord.

Variations of the IPG architecture shown in FIG. 4 may also be used. For example, one variation is to replace the current sources 186 and low impedance switching matrix 188 with a set of positive and negative current sources having discrete values, as shown in WO 00/00251 (International Application Number PCT/US99/14190).

That is, as taught in the WO 00/00251 publication, digital-to-analog converters (DAC's) are configured to source or sink a particular (programmed) current value. In such configuration, a programmable P-DAC (for sourcing current) and a programmable N-DAC (for sinking current) are connected at a common node to each coupling capacitor. That is, a first P-DAC/N-DAC pair is connected to capacitor C1, a second P-DAC/N-DAC pair is connected to capacitor C2, and so on, so that there are  $n$  P-DAC/N-DAC pairs for a system that employs  $n$  electrodes and  $n$  coupling capacitors. In use, a desired P-DAC and N-DAC are enabled (turned on so as to source or sink a programmed current value) when a desired current pulse is desired. Thus, for example, if a 4mA pulse is desired between electrodes E1 and E3, as shown at time  $t=0$  ms in FIG. 3, then the P-DAC associated with electrode E3 is programmed to source a 4 mA pulse at time  $t=0$  for 300  $\mu$ s, and the N-DAC associated with electrode E1 is programmed to sink a 4 mA pulse at time  $t=0$  for 300  $\mu$ s. All the other P-DAC's and N-DAC's are disabled (turned off) during this time.

In use, the IPG 100 is placed in a surgically-made pocket either in the abdomen, or just at the top of the buttocks, and detachably connected to the lead system (comprising lead extension 120 and electrode array 110). While the lead system is intended to be permanent, the IPG may be replaced should its power source fail, or for other reasons. Thus, a suitable connector is used to make the connection between the lead system and the IPG 100.

Once the IPG 100 has been implanted, and the implant system 10 is in place, the system may be programmed to provide a desired stimulation pattern at desired times of the day. The stimulation parameters are defined in an operational parameter set (OPS), which may also be referred to as an "operational parameter data set", or "controlling data" or "programming data." The parameters defined by and included within the operational parameter data set include the number of channels (defined by the selection of electrodes with synchronized stimulation), the stimulation rate and the stimulation pulse width. Also, the operational parameter data set defines the current output from each electrode by polarity and amplitude. Additionally, as indicated above, a run schedule may be defined in the operational parameter data set, which when used enables the IPG only at programmed times of the day.

The back telemetry features of the IPG 100 allow the status of the IPG to be checked. For example, when the external hand-held programmer 202 (and/or the clinician programmer 204) initiates a programming session with the implant system 10 (FIG. 1), the capacity of the battery is telemetered so that the external programmer can calculate the estimated time to recharge. Additionally, the electrode impedance measurements are telemetered at the beginning of each programming session, or as requested. Any changes made to the current stimulus parameters are confirmed

- 18 -

through back telemetry, thereby assuring that such changes have been correctly received and implemented within the implant system. Moreover, upon interrogation by the external programmer, all programmable settings stored within the implant system 10 may be uploaded to one or more external programmers.

5               Next, the clinician programming system will be described. This system includes, as seen in FIG. 1, a clinician programmer 204 coupled to a directional device 206. The clinician programmer 204 typically interfaces with a patient hand-held programmer (HHP) 202 in communicating with the implanted pulse generator (IPG) 100.

10              However, other types of communication links between the clinician programmer 204 (also referred to herein as a programming computer) and the IPG 100 may be utilized. It is the function of the present invention to quickly and easily identify an operational parameter data set and combination of electrodes, e.g., a particular electrode pair or grouping, that can be programmed into the memory of the IPG so as to produce a paresthesia in a region of the body that best matches a region of the body where the  
15              patient feels pain (or has another need for a stimulus to be applied to that body region).

              The programming system maintains a patient data base, and is able to program all features of the implant device in a simple and intuitive manner. Preprogrammed into the data base, along with information about the patient, is known information regarding anatomical relationships between the spine and the body.  
20              Additionally, the system allows threshold measurements to be made, operational electrodes to be identified, and is able to interface directly with the patient.

              A key feature of the SCS programming system is the use of a joystick accessory, or equivalent directional device 206 (FIG. 1), which allows the patient to interface with a laptop computer (e.g., programmed to function as the clinician  
25              programmer 204), or other processor (e.g., a hand-held computer, such as a PalmPilot® computer, or equivalent) so as to allow the patient, or other medical personnel assisting the patient, to configure electrodes and adjust various stimulation parameters and to identify regions of the body where pain is present and where a paresthesia is felt. One suitable directional programming device is described in more  
30              detail in United States Patent 6,052,624, entitled "Directional Programming for Implantable Electrode Arrays". As described in the '624 patent, such directional programming may advantageously be performed either in the operating room (OR) environment or in the doctor's office. The clinician or nurse simply operates the joystick feature, or equivalent directional programming feature, during surgery in conjunction  
35              with the trial stimulator 140 so as to configure and select the electrodes that provide desired stimulation. The patient then uses the joystick feature to finalize the device programming during a post implant adjustment session. Thus, whether communicating

with the trial stimulator 140 or with the IPG 100, the directional programming device 206 is able to be effectively used to configure which electrodes provide stimuli to the patient.

The directional programming device may take many forms. For purposes of the present invention, any device that allows a computer-generated cursor  
5 (or other indicator) to move about on the display screen of the computer as controlled by the user will suffice. Representative directional programming devices include keys on a keyboard (e.g., arrow keys), a mouse, a track ball, a touch-sensitive screen over which the users finger may be moved, voice commands in combination with voice recognition software, and the like.

10 In operation, as seen in FIG. 1, the clinician programming system communicates to the patient HHP 202 over a telecommunicative or other communication link 203, which then telemeters the data to the IPG 100. Likewise, the clinician's programmer is able to communicate to the trial stimulator 140 over the telecommunicative link 205. The communication links 203 and 205 are reliable links  
15 capable of operating in the busy OR environment. Data speeds to and from the IPG 100, through the patient programmer 202 intermediary link, are fast enough to not noticeably delay programming. A communication link status between devices is always depicted on a screen, or other display device, associated with the programmer 204.

As soon as the clinician programmer is initially connected to the implant  
20 system, hardware recognition occurs. That is, the system identifies the stimulator, the patient programmer, and electrode availability (through electrode impedance measurements).

For safety, the patient programmer 202 is coded to work only with a specific implant system. Should the patient lose his or her programmer 202, then the  
25 physician, using the clinician programmer, is able to code a new programmer for use with the patient's implant system. The clinician's programmer, in contrast, is able to communicate to any implant through any programmer 202 by using an overriding universal code. This allows the patient code to be extracted from the IPG 100 and used to re-code a new programmer 202.

30 When an IPG 100 is in contact with a clinician programmer 204, the device settings and hardware information (model, serial number, number of electrode by impedance, and the like) are first uploaded to the clinician programmer 204. All devices in the link with the IPG 100, e.g., the hand held device 202, and/or the trial stimulator 140, and clinician programmer 204, and the clinician programmer 204, are  
35 synchronized so that each device receives accurate and current data. Programming changes made to the stimulator(s) are confirmed through back telemetry or other means before the SCS add-on software reflects the change. Advantageously, the physician is able to program the stimulator through either the patient programmer 202 or the

- 20 -

clinician programmer 204 while linked together through the link 203, with all programming changes being mirrored in both devices.

Turning next to FIG. 5, one type of hand-held programmer (HHP) 202 that may be used as a component of the exemplary SCS system is illustrated. As seen in FIG. 5, the HHP 202 is housed within a hand-held case 220. Displayed on the case 220 are a set of intuitive control buttons 224, 225 that control the operation of the device. Advantageously, the HHP 202 is compact in size, and can be easily held in one hand. To make it even easier to carry, especially by the patient, a belt clip is placed on its back side, thereby allowing it to be worn on a patient belt, much like a pager or cell-  
10 phone. The device case includes an accessible battery compartment wherein replaceable (and/or rechargeable) batteries may be carried having sufficient capacity to provide operating power to its internal circuitry for at least one week.

The SCS system facilitates programming the stimulator, or IPG 100, through the use of a programming window that, when activated, is displayed by the clinician programmer 204 (FIG. 1). The programming window may, in one embodiment,  
15 include tiered sub-windows, which may be titled, e.g., "measurements", "programming", and "advanced". The programming window is advantageously accessible from both a main menu and a patient information window.

The measurement window, which may also be referred to as a  
20 "threshold" window, is used to set maximum and minimum thresholds, and to map pain and paresthesia with implanted electrodes to anatomical sites in accordance with the present invention. Salient features of a representative measurement window are illustrated in FIG. 6. As seen in FIG. 6, included in the display of the measurement window is a representation 230 of the type and orientation of the electrode array(s) that  
25 has/have been selected. Such selection is made from a group of possible electrode choices. Monopolar and bipolar sensitivity (max and min) thresholds are then determined for each electrode for the displayed electrode array configuration, with the aid of display portion 232.

Pain and/or paresthesia mapping is available to identify electrode effects  
30 through the threshold testing process. To aid in this process, a human figure 234 is displayed on the display screen associated with the programming computer. This human figure 234 is divided into body regions. Such body regions are also referred to, for purposes of the present invention, as "dermatones," "body subdivisions," "body areas," or similar language, as described more fully below in conjunction with the  
35 description of FIGS. 7A-7D.

In use, a pain or paresthesia is activated by toggling a color box, e.g., red or blue, that is superimposed over the affected body area. One color, e.g., is used to represent pain; while the other color, e.g. blue, is used to represent paresthesia. As the

cursor is moved over different body segments or regions, such segments change color to the active color and can be locked to the active color by clicking the mouse, or depressing a key or button. The paresthesia color is always transparent (top layered) so that pain segments can be seen. Multiple body segments can be selected  
5 individually, or as a group at intersections. By clicking on a segment, the active color is toggled off and on without affecting the alternate color. The object is to match or map the paresthesia segments with the pain segments. Such pain/paresthesia mapping feature may advantageously be used with expert algorithms to automate the programming process. Alternatively, the patient and clinician/physician may simply work  
10 together and use a trial-and-error procedure in order to best fit the paresthesia segments with the pain segments.

In order to explain in more detail how the pain/paresthesia mapping is performed, reference is next made to FIGS. 7A, 7B, 7C and 7D, where the human figure 234 displayed on the programming screen is shown in more detail. As seen in FIG. 7A,  
15 the human figure 234 is divided into a multiplicity different regions 239a, 239b, 239c, ... 239y. For purposes of the present invention, such regions 239a, 239b, ... 239y may also be referred to as "dermatones," "body subdivisions," "body areas," or similar language. While the human figure 234 shown in FIGS. 7A-7D is shown as being divided into twenty-five such regions 239 (239a through 239y), such number of regions  
20 is only exemplary.

To perform the pain/paresthesia mapping in accordance with the invention, the patient first identifies a region of pain. By way of example, in FIG. 7A, the patient has identified a region 240 (depicted in FIG. 7A as a right-slanting-hatched area, but preferably depicted on the programming screen in FIG. 6 by a different color, e.g.,  
25 red) as a region of pain. This pain region 240 comprises the two regions 239m and 239o on the left side of the patient comprising the lower back and pelvic areas. Such pain region 240 may be identified by simply moving the cursor over areas 239m and 239o and clicking a button, e.g., a mouse button or a keyboard button.

Once the patient has identified a pain region 240, the programming  
30 computer uses known data regarding the relationships between the electrode physical locations and the body to select a first electrode combination through which a stimulus of selected operating parameters may be applied. Once selected, a stimulus having the selected operating parameters is applied to the selected electrode combinations to test whether the resulting paresthesia is in the same location as the pain region 240. Thus,  
35 for example, after feeling or sensing the paresthesia, the patient identifies the location of the paresthesia on the human figure 234. By way of example, suppose the patient senses the paresthesia in a paresthesia region which is identified as region 242 in FIG. 7B. (depicted in FIG. 7B as a left-slanting-hatched area, but preferably depicted

- 22 -

on the programming screen in FIG. 6 by a different color, e.g., blue). The paresthesia area comprises the individual regions 239m, 239n and 239p, one region of which, 239m, overlaps with a portion of the pain region 240, but the other regions of which, 239n and 239p, do not overlap with the pain region 240.

5               Once the patient has identified the paresthesia region 242, the programming computer uses this information, in combination with other information stored therein, to determine what modification needs to be made to the stimulation parameters or electrode selection in order to steer the paresthesia region 242 (left-slanting-hatched area) over the pain region (right-slanting-hatched area). For example,  
10 the newly selected stimulus parameters, including the selected electrode combination, may produce a new paresthesia region 244 that moves over the pain region 240 but also extends down into the left leg into regions 239r and 239s, as shown in FIG. 7C. A subsequent iteration, i.e., the selection of a different electrode combination and/or the modification of the stimulus parameters produces a new paresthesia region 246 (left-slanting-hatched area) that matches, or merges with, the pain region 240, as illustrated  
15 in FIG. 7D.

Once a match has been obtained between the pain region and the paresthesia region, the programming data, e.g., the operating parameter set, including the selected electrode combination, may be programmed into the memory of the  
20 implantable pulse generator so that such data can thereafter be used to control the operation of the IPG, and to further aid in subsequent programming sessions.

The programming approach described above in connection with FIGS. 7A-7D is depicted in flow chart form in FIG. 8. As seen in FIG. 8, a first preliminary step associated with the method (block 260) involves creating a data base  
25 and storing such data base in the memory of the programming computer that maps various electrode combinations to paresthesia regions. Such data base may include data relating to known anatomical relationships between the spine and the body, as well as other known medical data.

Still with reference to FIG. 8, it is seen that the method includes  
30 displaying the human figure on a programming screen (block 262) divided into regions. The programming software that performs this function of displaying a human figure may be referred to as first program data. The patient then selects those regions (one or more) on the human figure which best represent the locations where he or she feels pain (block 264).

35               In response to the patient selection which identifies the pain region, the programming computer automatically selects an electrode combination and stimulation parameters which, according to its programming software, would best provide a paresthesia region for the patient that matches the identified pain region (block 266).

- 23 -

The data in the data base stored in the computer (block 260) aids in this process. For example, the data in the data base may indicate that if pain is identified in location "X" (which X is any of the regions 239a, 239b, 239c, ... shown in FIG. 7A), then a stimulus should be provided through electrode "Y", where electrode "Y" is one of the electrodes connected to the IPG. The stimulus parameters may initially be selected as nominal parameters. Selection algorithms, implemented in software or firmware within the computer, may be readily fashioned by those of skill in the art to automatically make this initial selection. The programming software that performs the function of making the initial electrode and stimulus parameter selection may be referred to as second program data.

Still with reference to FIG. 8, once the electrode combination and stimulation parameters have been initially selected, then the programming computer generates the appropriate command signals to cause the implantable pulse generator (IPG) to stimulate the patient through the selected electrode combination (block 268). As a result of such stimulation, the patient senses a region of paresthesia, and is thus able to identify the region of paresthesia on the displayed human figure (block 270). The programming computer, using an appropriate algorithm which may be referred to as third program data, determines the degree of mismatch between the pain region and paresthesia region (block 272). Such matching algorithm, in one form, simply quantifies the amount of overlap between the identified paresthesia region and the selected pain region using the defined regions 239a, 239b, 239c, ... (see FIG. 7A) on the human figure. Other, more sophisticated matching algorithms, as are known in the art, may also be used for this purpose.

If the degree of mismatch between the paresthesia region and the pain region exceeds a prescribed threshold, e.g., if the mismatch is greater than 80% (or any other selected percentage), i.e., if only 20% of the pain region overlaps with the paresthesia region, then a further iteration of selecting a new electrode combination and/or stimulus parameters, is needed. Such further iteration involves having the programming computer select a new electrode combination and stimulation parameters (block 278). Such selection is made based on the paresthesia region information provided by the patient and other data stored in the data base. For purposes of the invention, such information and data may be referred to as fourth program data. The fourth program data will typically comprise the second program data referred to above, modified in accordance with the paresthesia region information provided by the patient. It is the function of the fourth program data to modify the electrode combination and stimulation parameter selection so as to move the paresthesia region closer to the pain region, so that eventually the two regions merge or overlap.

- 24 -

As shown in FIG. 8, an optional step that may be used with the method shown in FIG. 8, once a determination has been made that the mismatch between the paresthesia region and the pain region exceeds a prescribed threshold (block 272), i.e., that there is not a match between the two regions, is to determine whether the paresthesia region covers more than one region (block 274). That is, a determination is made as to whether the paresthesia region includes more than one of the regions defined in the human figure. For example, as shown in FIG. 7B, the initial paresthesia region 242 includes three defined regions on the human figure, regions 239m, 239n and 239p. In such instance, an option associated with the invention allows the patient to identify the relative strength of the paresthesia in each region (block 276). That is, the patient may indicate whether the paresthesia sensed in human figure region 239m is stronger than the paresthesia sensed in human figure regions 239n or 239p. Such comparative paresthesia strength data is then used by the programming computer, when available, to guide the new selection of electrode combinations and stimulation parameters (block 278).

If the degree of mismatch between the paresthesia region and the pain region is less than a prescribed threshold, e.g., if the mismatch is less than 10% (or any other selected percentage), i.e., if 90% of the pain region overlaps with the paresthesia region, then a match condition is assumed (YES branch from block 272). In such instance, the electrode selection and stimulation parameters that resulted in such match condition may be sent to and stored in the IPG, or other implant device, to control the operation of the device in a manner that regularly overlays the paresthesia region on the pain region. With the programming of the implant device, the data base created in the computer memory is preferably updated with the data that produced the match condition. Should the pain region move over time, then the programming process shown in FIG. 8 can be repeated, as required.

Thus, it is seen that the method shown in FIG. 8, or variations thereof, provides a method for programming a device for use with an implantable stimulator, such as an implantable spinal cord stimulator. Such method allows the patient to easily identify a region of pain and then a region of paresthesia, so that the programming device may then automatically change the selected stimulation parameters, including the selected combinations of electrodes, to cause the region of paresthesia to overlap or merge with the region of pain, thereby alleviating the pain.

Returning to FIG. 6, it is noted that the main programming window screen may be used to program electrode configurations and the desired output parameters for each of the available channels, e.g., each of four channels. To illustrate how this is done, consider area 236 of the screen shown in FIG. 6. All four channels are selectable from this screen. The channels are selected for programming by pointing and clicking

- 25 -

using a mouse or other similar pointing/selection device. The default selection is the first channel. Selecting a channel causes the output parameters and electrodes for that channel to be displayed, so that they can be manipulated. Once selected, continual clicking of the channel toggles stimulation between active ON and PAUSED, with a  
5     settable soft start. Selection of another channel does not change any of the settings of a previous channel. A channel that has been selected as an active ON channel is represented by stimulation pulses, see area 238. Channels are identified by number, but can also be selectively or automatically named by paresthesia location (i.e., legs, back, left arm, etc.) from mapping functions.

10             Before electrodes are displayed on the screen for programming, the array type and orientation must be selected. The number of implanted and available electrodes is typically automatically determined by impedance measurements during hardware interrogation. Pointing to the electrode box 230 provides an electrode array  
15     the array configuration is selected, it is displayed on the screen with point and click selectable electrodes. For example, one click may be used to specify a cathode; two clicks to specify an anode; and a third click to specify a neutral (floating or non-connected) electrode. Cathode, anode and neutral selections are indicated by a color change. By clicking an electrode to a cathode or anode state, the electrode is assigned  
20     to the active channel. If desired, a representation of current fields created by electrodes of a channel may also be displayed within this representation.

              The amplitude, pulse width and rate are adjustable by mouse or arrow keys for the selected channel, using e.g., the "channel settings" area 232 of the programming screen. Amplitude, on this main programming screen, is programmable  
25     by channel, and applied as either a current value, e.g., 4 mA, or as a distribution between maximum and sense thresholds for channel assigned electrodes. The pulse width and rate are also selectable for the channel, and applied to the channel-assigned electrodes. Although the programming software permits a physician to program electrodes by channel, each electrode is individually controlled by the implant, and  
30     telemetered data is electrode specific. When a channel is programmed to stimulation rates over 150 pps, the number of additional channels may be limited (due to battery capacity).

              The settings for up to four channels are referred to as a "program." Selectable default parameter settings may thus comprise a program. A store/apply  
35     button records all the settings with a program number. Up to twenty programs can be named, stored and selected from a drop-down program list. Thus, programs may be sequentially or selectively tried by the patient so that the patient may compare how one "program" feels compared to another.

Any changes in programming are duly considered relative to the effect they will have on a projected battery discharge cycle. Should a programming change fall below a two day recharge and/or less than a three year expected life, a pop-up window appears with suitable warnings and possible recommendations. As needed, an  
5 emergency off button turns all stimulation OFF, with direct keyboard and mouse click access.

It is thus seen that the programming window allows the output parameters for each channel to be programmed with additional capability and specificity. For example, biphasic verses passive balance pulses, active multipolar driving of  
10 cathodes and anodes (field focusing), and amplitude selection for individual electrodes.

Unique programming algorithms may also be employed which provide, e.g., automated and directional programming features. Automated programming may be used, e.g., to use known thresholds and pain/paresthesia mapping to recommend configurations and parameters based on preset rules and database information.  
15 Automated programming maps paresthesia sites over pain sites. Directional programming features may be as disclosed, e.g., in United States Patent 6,052,624, previously referenced. Such directional programming uses a joystick, or other means, to configure electrodes within certain limitations for selection, polarity, and amplitude distribution in response to a directional input and in an intuitive and physiologic manner.

Advantageously, the programming software used within the clinician programmer 204 (FIG. 1), also referred to herein as the programming computer, may run under conventional operating systems commonly used within personal computers (PCs). The preferred clinician programmer is a Pentium-based PC, operating at 100  
20 MHz or more, with at least 32 Mbytes of RAM. Examples of an operating system for use in such a system include Windows 95/98/00 or Windows NT 4.0. Such programming software also supports multiple languages, e.g., English, French, German, Spanish, Japanese, etc.  
25

While the invention herein disclosed has been described by means of specific embodiments and applications thereof, numerous modifications and variations  
30 could be made thereto by those skilled in the art without departing from the scope of the invention set forth in the claims.

- 27 -

**CLAIMS**

What is claimed is:

1. A method of programming an implant device, the implant device comprising an implantable pulse generator having an implantable electrode array  
5 connected thereto, the implantable pulse generator having electrical circuitry therein that generates electrical stimulation pulses in accordance with programming data, which electrical stimulation pulses are delivered to body tissue of a patient through a selected combination of a multiplicity of electrodes on the electrode array, wherein the programming method comprises:
  - 10 (a) creating a data base that maps various electrode combinations to paresthesia regions of the body;
  - (b) storing the data base in a programming computer;
  - (c) displaying a human figure on a screen of the programming computer, and dividing the human figure into a multiplicity of regions;
  - 15 (d) selecting at least one region on the displayed human figure where the patient feels pain;
  - (e) selecting a combination of electrodes and stimulation parameters adapted to produce paresthesia in the same at least one region of pain;
  - (f) generating stimulation pulses and delivering the stimulation pulses to the  
20 selected combination of electrodes through the implantable pulse generator;
  - (g) identifying at least one region of paresthesia on the displayed human figure where the stimulation pulses generated in step (f) produce paresthesia;
  - (h) determining the degree of mismatch between the at least one region of paresthesia identified in step (f) and the at least one region of pain selected in step (d);
  - 25 (i) if the degree of mismatch exceeds a prescribed level, selecting a new combination of electrodes and stimulation parameters based on the identified at least one region of paresthesia and the degree of mismatch, and repeating steps (f), (g) and (h); and
  - (j) if the degree of mismatch is less than the prescribed level, programming  
30 the implantable pulse generator with the programming data that produces the least mismatch.
2. The method of programming set forth in Claim 1 wherein steps (c), (e), (f), (h), (i) and (j) are carried out automatically by a programming computer as controlled by an operating program and program data stored in the programming computer.

- 28 -

3. The method of programming set forth in Claim 2 wherein steps (d) and (g) are performed by selecting regions on the displayed human figure by manually moving a computer-generated cursor over the region to be selected.

4. The method of programming set forth in Claim 3 wherein moving the cursor is accomplished by at least one of the following: pressing a key, moving a mouse, moving a track ball, moving a finger over a touch-sensitive screen, and speaking voice commands.

5. A system for programming an implantable pulse generator having an implantable electrode array connected thereto, and wherein the implantable pulse generator has electrical circuitry therein that generates electrical stimulation pulses in accordance with programming data, which electrical stimulation pulses are delivered to body tissue of a patient through a selected combination of a multiplicity of electrodes on the electrode array, wherein the system for programming comprises a programming computer linked to the implantable pulse generator, the programming computer having a display screen, and means for generating a cursor on the screen that may be manually moved about the screen by a user, wherein the programming system is characterized by:

means for displaying a human figure on a screen of the programming computer, the human figure being divided into a multiplicity of regions;

means for selecting at least one region on the displayed human figure where the patient feels pain;

means for selecting a combination of electrodes and stimulation parameters adapted to produce paresthesia in the same at least one region of pain;

means for generating stimulation pulses and delivering the stimulation pulses to the selected combination of electrodes through the implantable pulse generator;

means for identifying at least one region of paresthesia on the displayed human figure where the generated stimulation pulses produce paresthesia;

means for determining the degree of mismatch between the identified at least one region of paresthesia and the selected at least one region of pain;

means for selecting a new combination of electrodes and stimulation parameters based on the identified at least one region of paresthesia and the degree of mismatch if the degree of mismatch exceeds a prescribed level and determining a new degree of mismatch with the newly selected combination of electrodes and stimulation parameters, whereby the degree of mismatch may be minimized; and

- 29 -

means for programming the implantable pulse generator with the programming data that produces the least mismatch.

6. The programming system set forth in Claim 5 wherein the means for displaying a human figure, means for selecting a combination of electrodes and stimulation parameters, means for generating and delivering stimulation pulses, means for determining the degree of mismatch, and means for selecting a new combination of electrodes and stimulation parameters when the degree of mismatch exceeds the prescribed level, operate automatically by the programming computer as controlled by an operating program and program data stored in the programming computer.
7. The programming system set forth in Claim 6 wherein the means for selecting at least one region where the patient feels pain and the means for identifying at least one region of paresthesia comprise means for moving a computer-generated cursor over the region to be selected and means for making a selection when the cursor is over the region to be selected.
8. The programming system set forth in Claim 7 wherein the means for moving a computer-generated cursor over the region to be selected and making a selection includes at least one of the following: a pressable key, a movable mouse, a movable track ball, a touch-sensitive screen, a light-beam sensitive screen, or means for recognizing spoken voice commands.

1/8

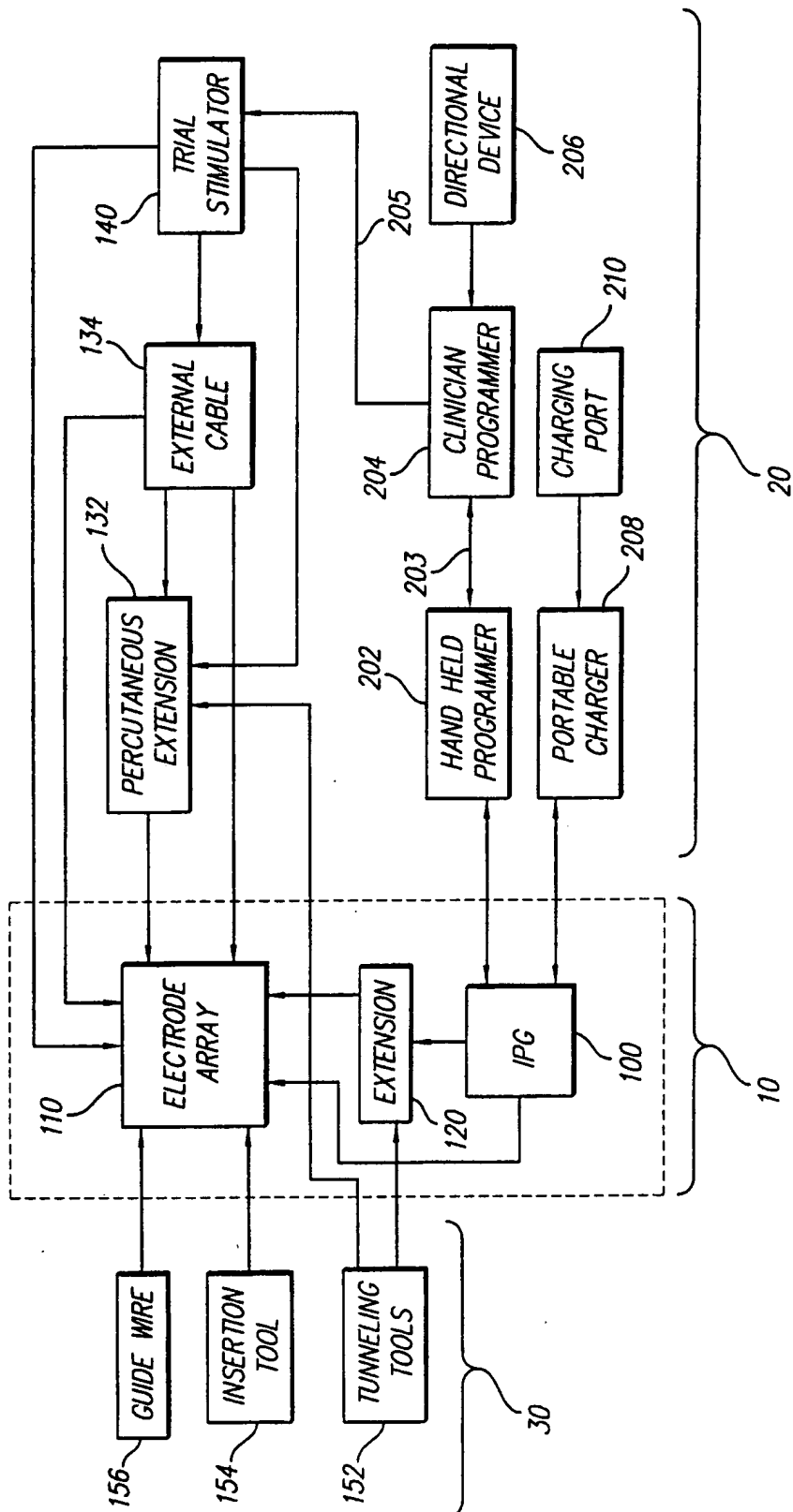
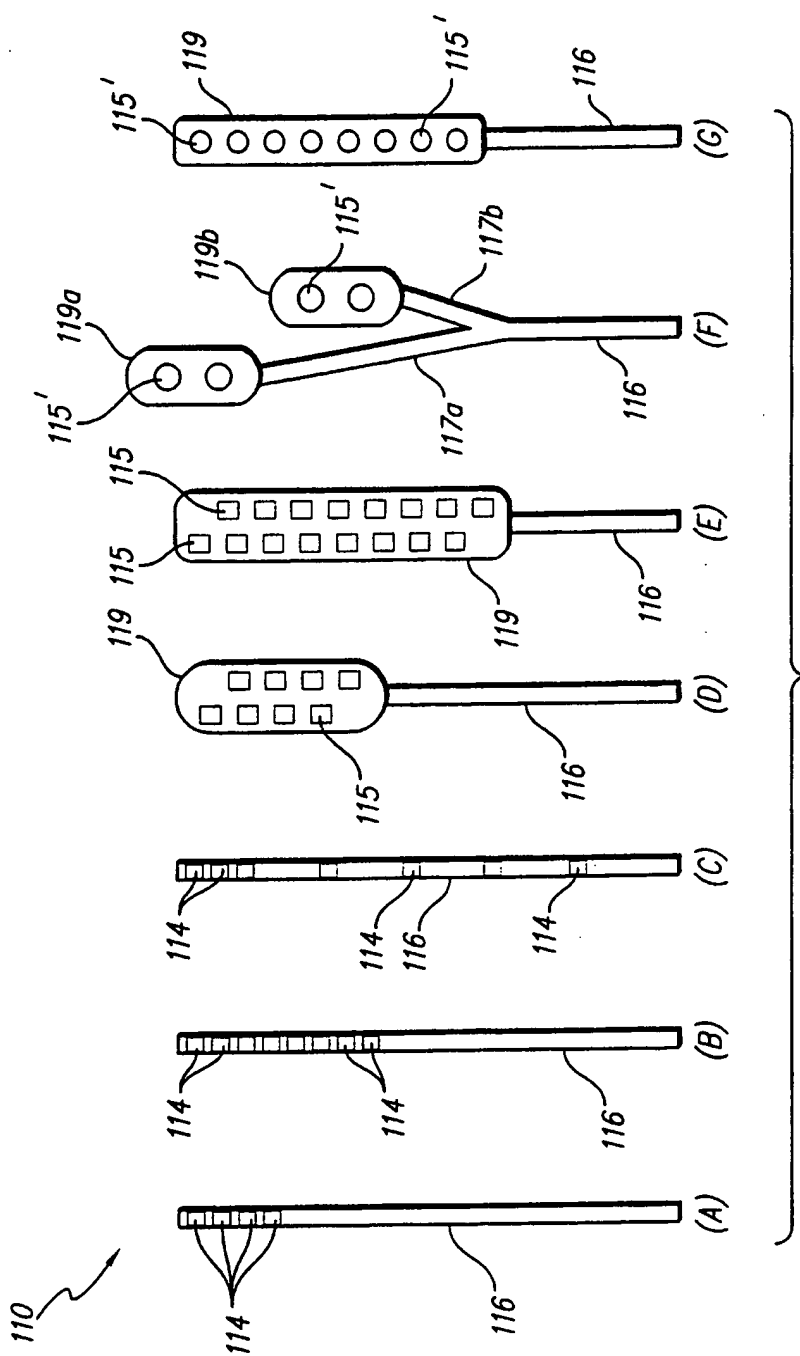
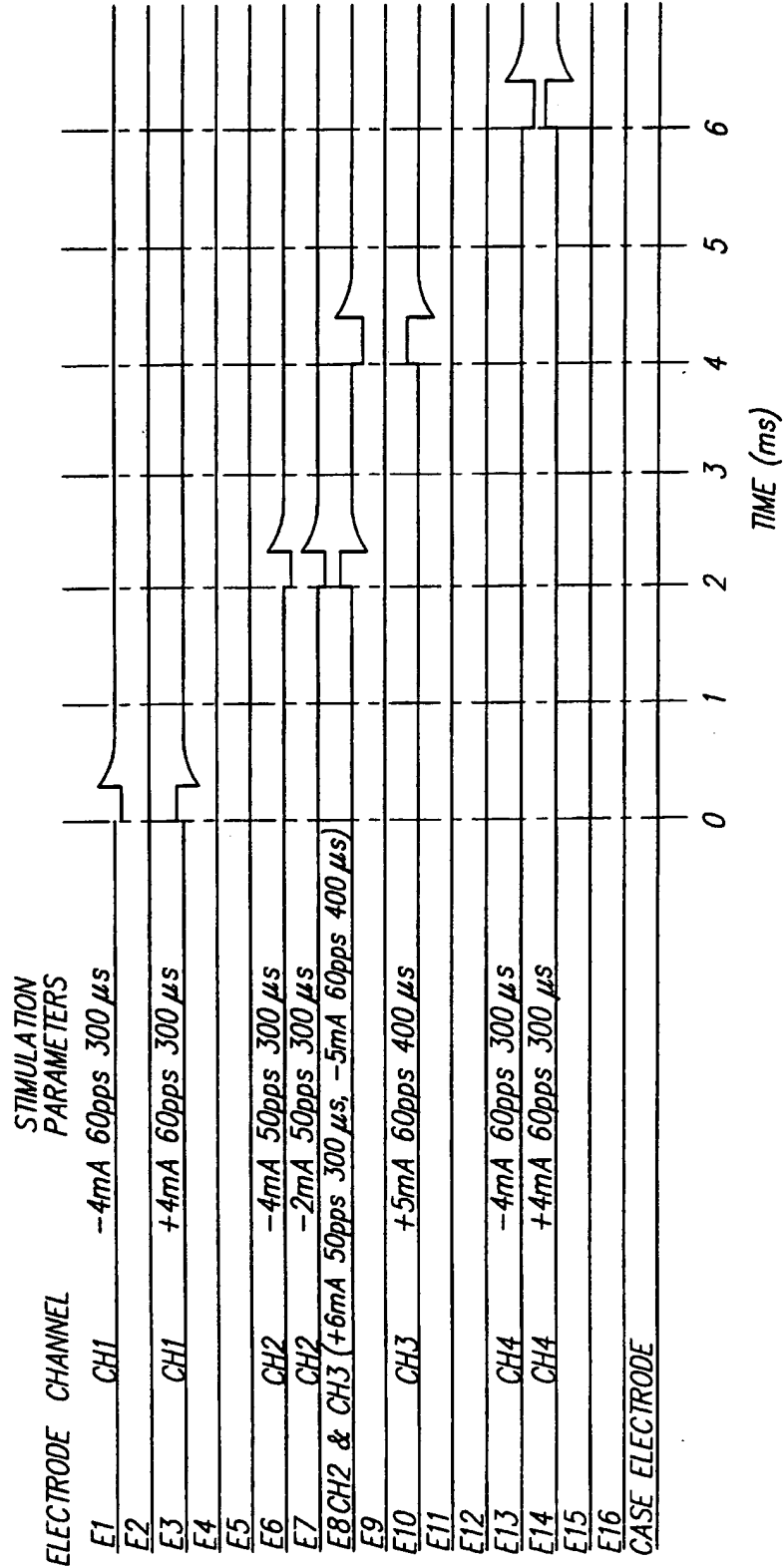


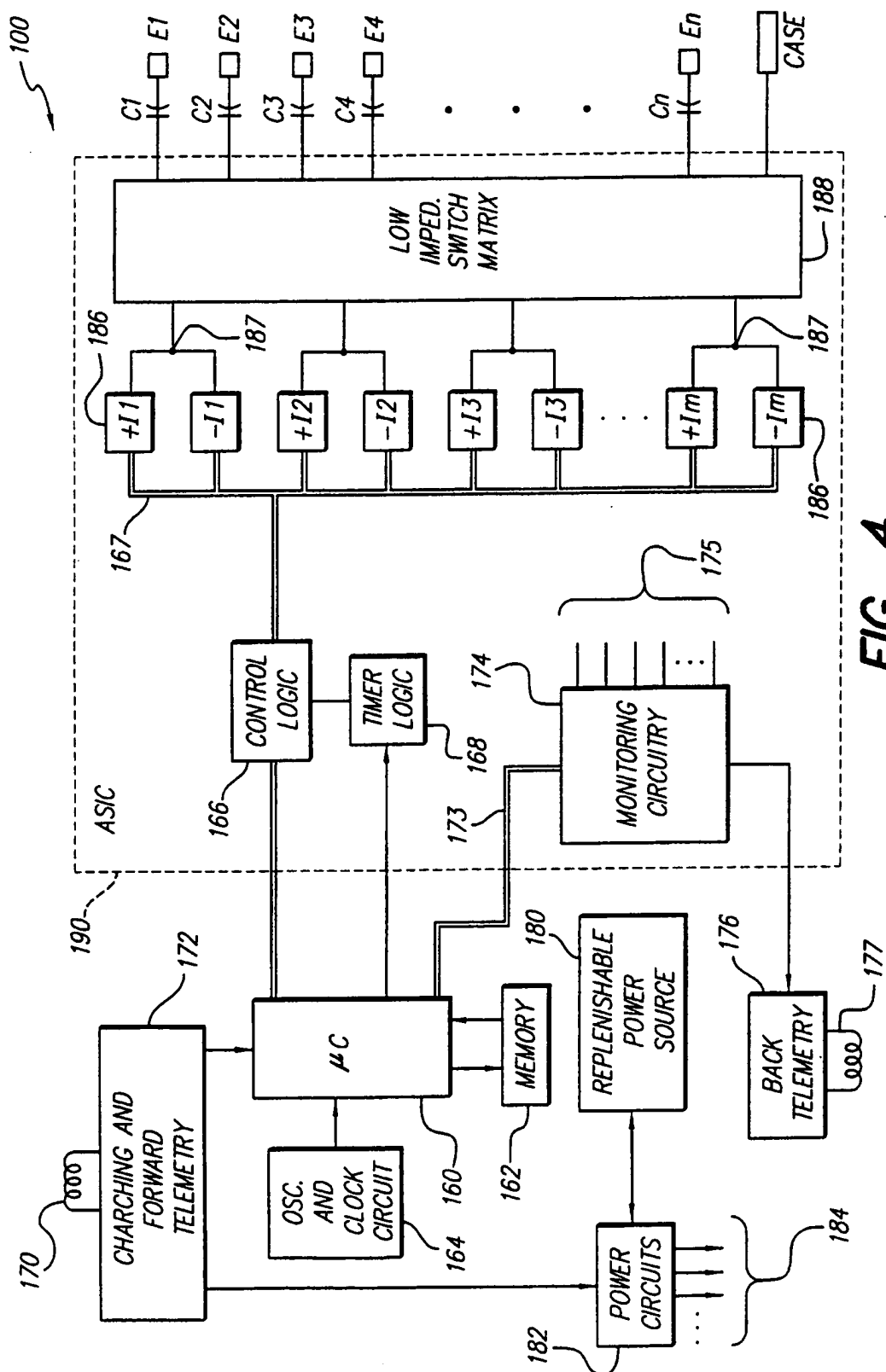
FIG. 1



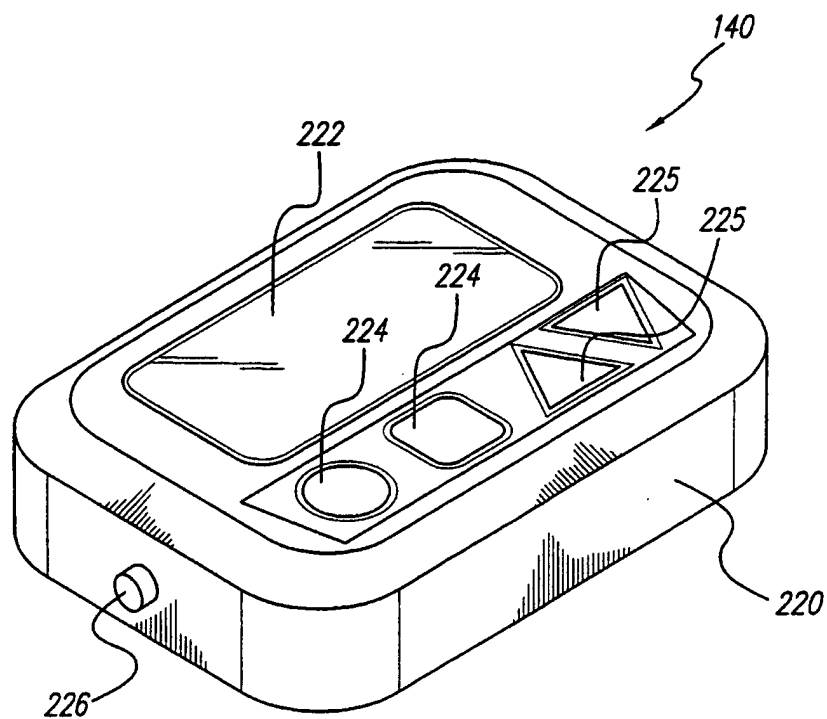
3/8

FIG. 3





**FIG. 4**



**FIG. 5**

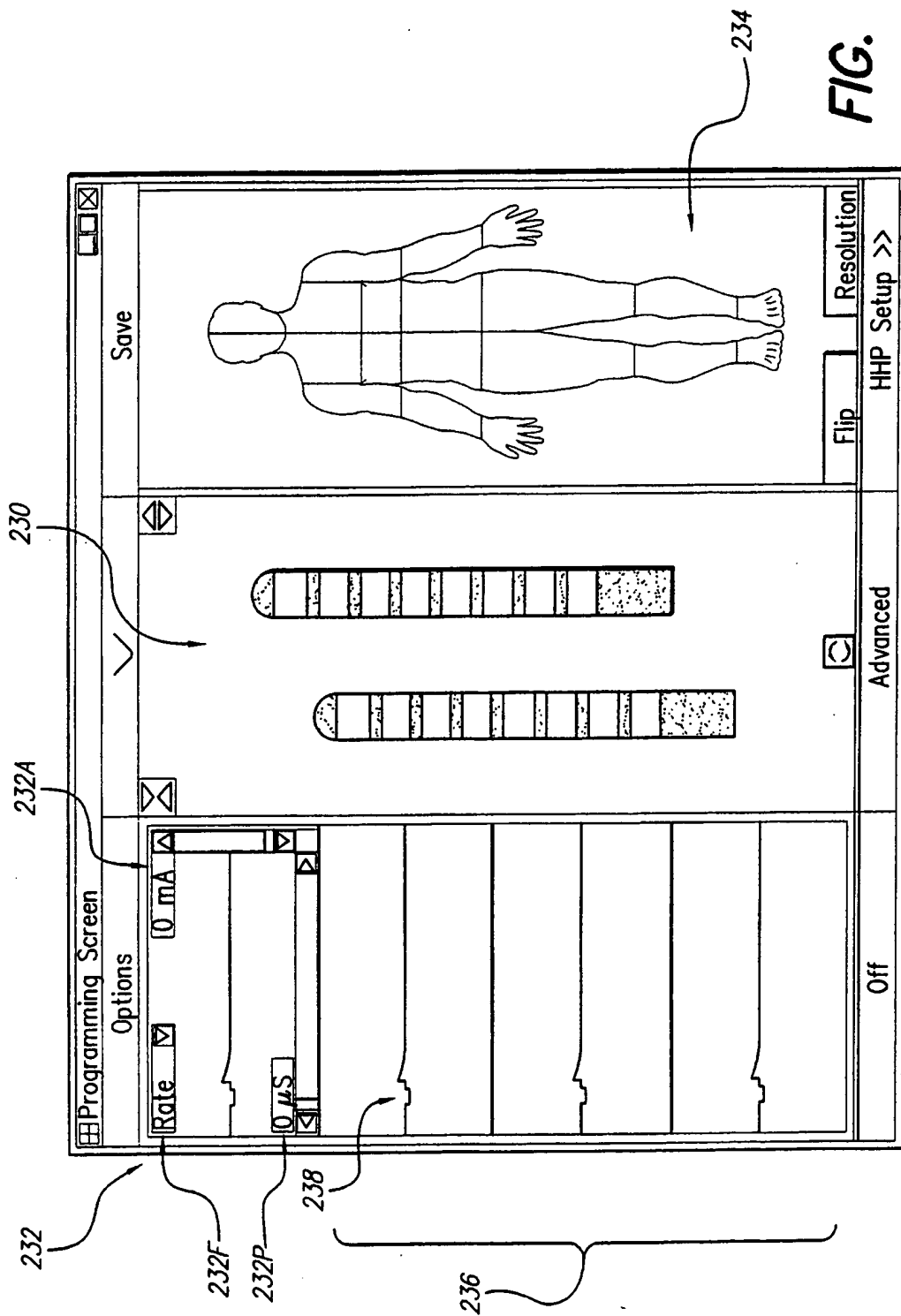


FIG. 6

7/8

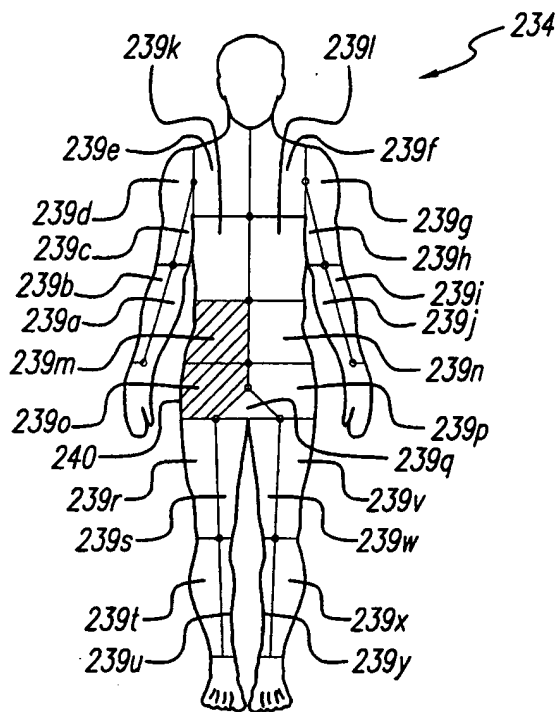


FIG. 7A

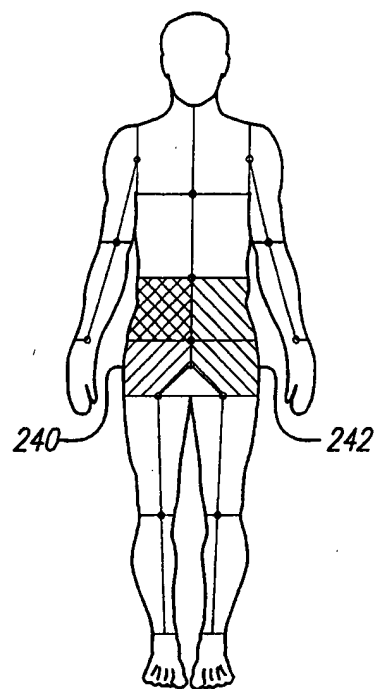


FIG. 7B

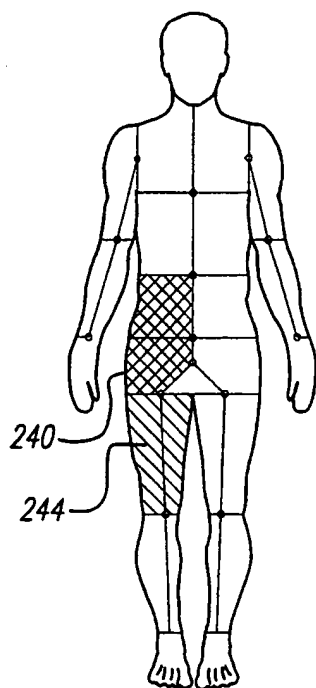


FIG. 7C

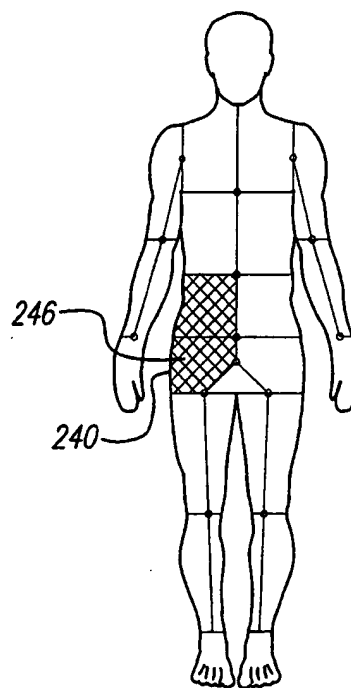
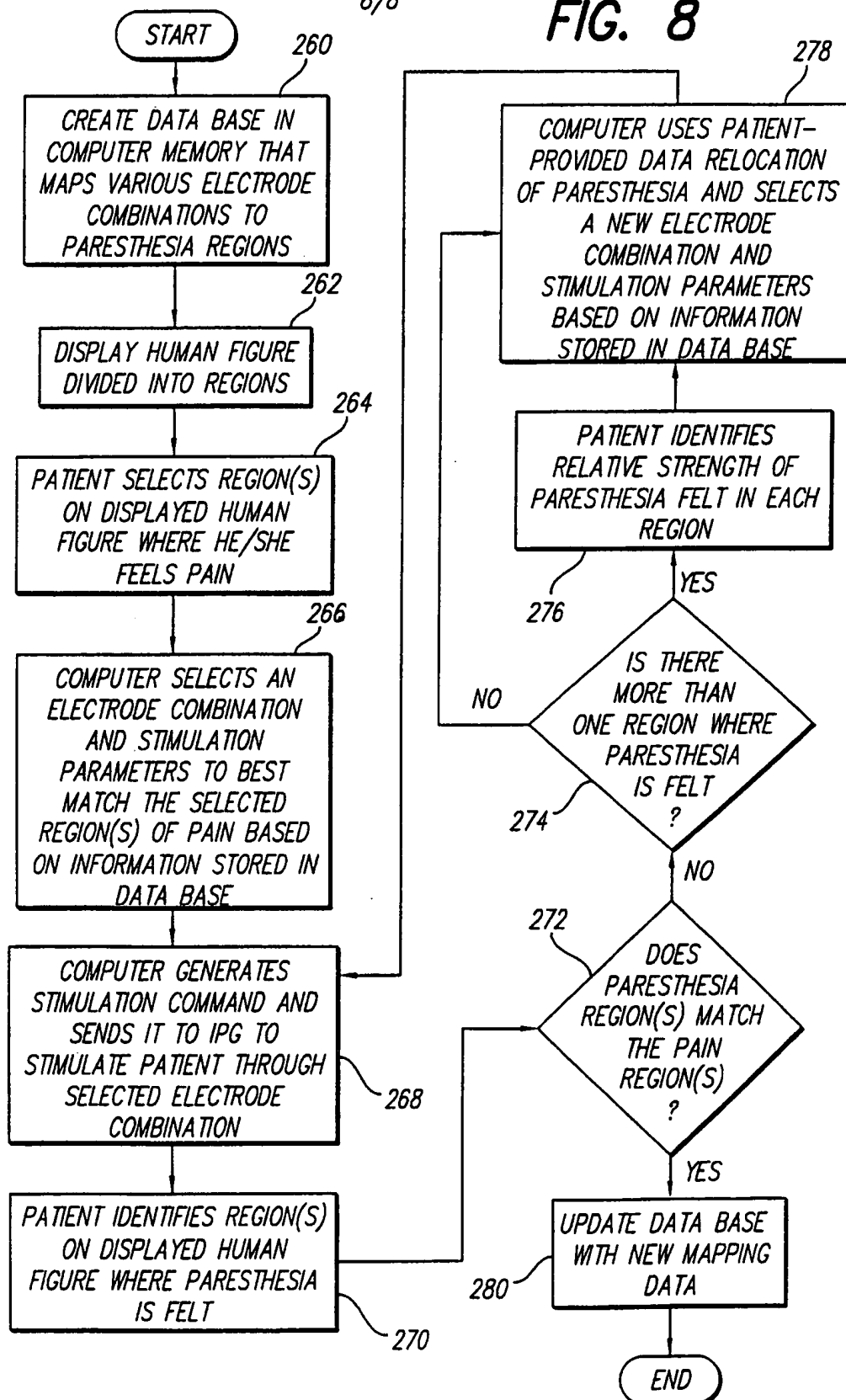


FIG. 7D

8/8

FIG. 8



# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 00/31612

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61N1/372 A61N1/34

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 370 672 A (FOWLER KIM R ET AL) 6 December 1994 (1994-12-06) column 4, line 55 -column 5, line 28 -----	5,6 7,8

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

5 February 2001

Date of mailing of the international search report

12/02/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Grossmann, C.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/31612

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5370672    A	06-12-1994	NONE	